REF ARI-MCI-32

MyCare Insite Total Aripiprazole Test

INDICATIONS FOR USE

The MyCare Insite Total Aripiprazole Test is intended for the *in vitro* quantitative measurement of total aripiprazole (aripiprazole plus dehydroaripiprazole) in finger capillary blood using the automated MyCare Insite. The MyCare Insite Total Aripiprazole Test is designed to be used either in a clinical laboratory or in the near patient setting by trained health-care professionals.

SUMMARY AND EXPLANATION OF THE TEST

Aripiprazole (7-[4-[4-(2,3-dichlorophenyl)-1-piperazinyl]butoxy]-3,4-di-hydrocarbostyril) is a quinolone derivative atypical antipsychotic agent. It has partial agonistic activity at dopamine D2 receptors and serotonin 5-HT1A receptors and potent antagonistic activity on serotonin 5-HT2A receptors.[1,2] The oral medication is indicated for the treatment of schizophrenia, acute treatment of manic and mixed episodes associated with bipolar disorder, adjunctive treatment of major depressive disorder, irritability associated with autistic disorder, and Tourette's disorder. The injectable is indicated for agitation associated with schizophrenia or bipolar mania. The major metabolite of aripiprazole, dehydroaripiprazole, is also pharmaceutically active.[1] The therapeutic effect of aripiprazole is due to the total exposure to both aripiprazole and the active metabolite (dehydroaripiprazole).[3] The total aripiprazole assay measures the total active aripiprazole in patient blood: aripiprazole plus dehydroaripiprazole.

Nonadherence to medication is well known for patients with severe mental illness.[4] While adherence to medication is critical to successful treatment outcomes, adherence is also least likely to be accurately assessed by clincians.[5,6] Measurement of total aripiprazole provides clinicians with objective evidence of concentrations that may be related to patient adherence.[7]

The MyCare Insite Total Aripiprazole Test is a homogenous two reagent nanoparticle agglutination assay used for detection of total aripiprazole in human blood. It is based on competition between drug and drug-conjugates for binding to drug specific antibodies that are covalently bound to nanoparticles. The extent of particle aggregation can be measured photometrically on the MyCare Insite.

TEST COMPONENTS

The Test components, Cuvettes, Reagent Caps, and RFID card are color-coded green. Always match the Cuvette, Cap, and RFID colors. The RFID card should be used with the tests it comes with.

MyCare Insite Total Aripiprazole Test REF ARI-MCI-32	Amount
MyCare Insite Cuvette – Single Use Reaction buffer that contains drug-conjugate, protein, and buffer	32 x 0.95 mL per test
MyCare Insite Reagent Cap - Single Use Nanoparticle component that contains monoclonal antibody bound to nanoparticles in a buffered solution	32 x 0.20 mL per test
MyCare Insite Total Aripiprazole RFID Card	1 per test box

WARNINGS AND PRECAUTIONS

- For *In Vitro* Diagnostic Use Only.
- For diagnostic purposes, the results should always be assessed with the patient's medical history, clinical examination, and other findings.
- Values obtained with different assay methods cannot be used interchangeably due to differences in methodology. Consistent use of one assay for an individual patient is recommended.
- Exercise normal precautions for handling laboratory tests.
- All components of the aripiprazole test contain less than 0.1% sodium azide. Do not swallow. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Seek immediate medical attention if tests are ingested or come into contact with eyes. When disposing of tests, always flush with large amounts of water to prevent accumulation of azide.

TEST HANDLING

IMPORTANT

Remove the Reagent Cap and Cuvette from the test box and place in the Test Rack to come to room temperature.

Reagent Cap and Cuvette must be at room temperature (20 - 25°C) to perform a test.

Allow the test(s) at least 10 minutes to come to room temperature (20 - 25°C).

If liquid is spilled from the Cuvette, DO NOT USE. Use a new Cuvette.

STORAGE AND STABILITY

Store the tests refrigerated at 2 – 8°C.

Cuvettes should be stored upright. If a closed Cuvette is tipped over, tap the Cuvette 2 – 3 times on the benchtop to ensure there is no liquid stuck to the Cuvette stopper.

Cuvettes and Reagent Caps may be used until the expiration date.

The RFID card may be used with the tests until the expiration date. The RFID card should only be used with the tests it comes with. Keep the RFID card with the test box.

Do not freeze.

SPECIMEN COLLECTION AND HANDLING

Capillary blood from a finger stick is required.

Trough or C_{min} samples at steady state have been recommended for testing antipsychotics.[6] After two weeks of treatment on the same dose, collect samples before the next dose.[8] For long lasting injectables, collect the sample before the next dose.[7]

Before collecting the sample remove the stopper from the Cuvette; discard the stopper. If the Cuvette cracks, discard and use a new Cuvette. Return Cuvette to the Test Rack provided with the MyCare Insite.

Use standard capillary blood collection techniques to produce a blood drop on the patient's finger.[9,10]

Collect 20 µL of capillary blood using a 20 µL capillary. Hold the capillary at an angle below the drop of blood (Figure 1). When the capillary is completely filled it contains exactly 20 µL.

Ensure that the capillary is completely filled (Figure 2) with blood and there is no blood on the outside of the capillary. The capillary may be wiped with a clean lint-free cloth to remove excess blood on the outside of the capillary.

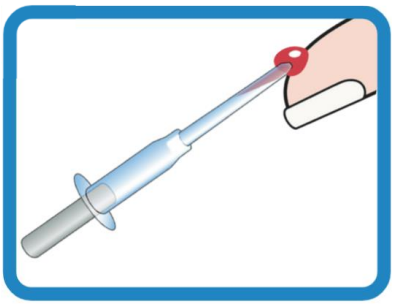

Figure 1

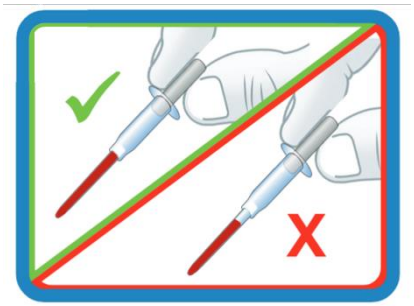

Figure 2

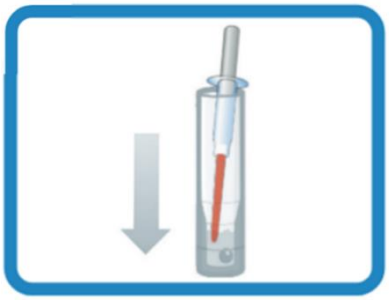

Figure 3

Immediately (within 30 seconds) add the blood from the capillary into the Cuvette (Figure 3). Place the capillary just in the liquid and dispense by slowly depressing the capillary plunger. Ensure all blood is transferred.

Place the Reagent Cap on the Cuvette immediately (within 15 seconds) of adding the sample. Firmly snap the Reagent Cap in place to tightly close the Cuvette. The Cuvette containing sample and sealed with the Reagent Cap is used as a test cartridge. The test cartridge must be measured within 6 hours of collection.

Place the cartridge in the Analyser Chamber and immediately (within 10 seconds) close the door to start the measurement.

PROCEDURE

Materials Provided:

REF ARI-MCI-32 - MyCare Insite Total Aripiprazole Test with Total Aripiprazole RFID Card

Materials Required – Provided Separately:

REF MCP2-CON - MyCare Psychiatry Control Kit 2

REF MCI-EUR - MyCare Insite (MyCare Insite Analyser laboratory photometer and MyCare Insite Touch Screen)

Materials Required – Not Provided

Finger stick lancets (e.g. 21 G x 2.0 mm, single use safety lancet)

20 µL (neutral, white) Sarstedt Minivette® POCT capillary for blood collection (Order No. 17.2111.020)

Pipette for 20 µL

Calibration

The manufacturer's calibration is stored on the RFID card that is included in the test box.

Quality Control (QC)

All quality control requirements and testing should be performed in accordance with local, state and/or federal regulations or accreditation requirements.

QC testing ensures that the calibration stored on the RFID card is valid.

QC testing is recommended when:

- Testing patient samples (at least once a week)

- A new test box is opened
- A new shipment or lot is used
- There is an unexpected patient result
- New users are trained
- The Insite is installed

Preparing to measure

1. For each test to be performed, place a Cuvette and Reagent Cap in the Test Rack.
2. Allow at least 10 minutes to warm to room temperature.
3. Refer to the MyCare Insite User Manual PI MCI-EUR-ML-PKG for steps to prepare the MyCare Insite to measure a patient sample.
4. Remove the stopper from the Cuvette, discard the stopper, and place the Cuvette back into the Test Rack.

Collecting a sample - See Specimen Collection and Handling

Testing a sample - Refer to the MyCare Insite User Manual PI MCI-EUR-ML-PKG for steps to test a patient sample on the MyCare Insite.

Measuring QC

A control is run in the same way as a patient sample. Only the medium control of the MyCare Psychiatry Control Kit 2 should be used for quality control of the MyCare Insite Total Aripiprazole Test. Transfer exactly 20 µL of medium control into a Cuvette with a pipette. Place the Reagent Cap in the Cuvette. Firmly snap the Reagent Cap in place to close the test cartridge. The Cuvette containing sample and sealed with the Reagent Cap is used as a test cartridge. The test cartridge is now ready to measure.

Compare the QC result to the range in the MyCare Psychiatry Control Kit 2 package insert (MCP2-CON). If the result is not in range, perform the following:

1. Verify that the control materials have been stored according to the directions and that the open vial stability duration and expiration date have not been exceeded.
2. Verify that the handling and testing procedures were performed according to the directions in the package insert, instructional wall chart, or video at MyCareInsite.com.
3. Verify that the operator had passing control results during training.
4. Repeat the control test, using a new control from the same lot.

If all instructions have been followed but control results are still not within range, please contact your Official Saladax Distributor for assistance before testing any patient samples.

RESULTS

The concentration result is automatically calculated from the manufacturer's calibration on the RFID card. Results are reported from 0 to 1,200 ng/mL (1.200 mg/L). Below the LoQ, the Total Error of the test is > 35%; consider this when evaluating results.

Test results > 1,200 ng/mL should be repeated. If the second result is in the assay range, report the second result. If the repeat result is > 1,200 ng/mL, report result as > 1,200 ng/mL.

Interpret results in accordance with recommendations in the published literature.[7,11-13]

For diagnostic purposes the test findings should always be assessed in conjunction with the patient's medical history, clinical examinations, and other findings.

Values obtained with different assay methods cannot be used interchangeably due to differences in methodology. Consistent use of one assay for an individual patient is recommended.

The reference range for total aripiprazole is not fully established. A reference range from 150 to 500 ng/mL has been proposed for aripiprazole plus dehydroaripiprazole.[7] Clinicians using reference ranges should be

aware that patients may achieve therapeutic benefit with drug concentrations outside of these ranges and may experience toxicity with levels below the lower limit of the reference range.

Clinicians should carefully monitor patients during therapy initiation and dose adjustments. It may be necessary to obtain multiple samples, including establishing a baseline, to determine expected optimal (steady-state) concentrations for individual patients.[11]

Compare test results to expected results based on previous measurements, subject's baseline, suggested reference range, or values expected for the individual. Consult the references above for guidance.

LIMITATIONS OF THE PROCEDURE

Use only capillary whole blood obtained by finger stick.

As with any test utilizing mouse antibodies, the possibility exists for interference by human anti-mouse antibodies (HAMA) in the sample. Samples containing such antibodies can potentially produce erroneous aripiprazole results, which are inconsistent with the patient's clinical profile.

For samples containing 150 and 500 ng/mL total aripiprazole, 50 ng/mL of cariprazine caused assay biases of 164% and 71%, respectively, and 42,000 ng/mL of lamotrigine (3X the therapeutic level) caused assay biases of 40%. Elevated levels of aripiprazole may be seen in patients administered cariprazine or lamotrigine.

SPECIFIC PERFORMANCE DATA

Typical performance data for the total aripiprazole test using multiple MyCare Insites and operators are shown below. Results obtained by individual users may differ from these data.

Precision

Within-laboratory precision and repeatability were verified throughout the measuring range according to CLSI Guideline EP05-A3.[14] One Control Kit 2 control, four total aripiprazole spiked whole blood samples (Spikes 1, 2, 3, 4), and one aripiprazole spiked buffer sample (Spike 5) were tested. Testing included 6 different operators and 36 MyCare Insites.

Sample	N	Mean (ng/mL)	Repeatability	Within-Laboratory
			CV	CV
Control	80	215	3.1%	5.1%
Spike 1	80	68	6.3%	11.1%
Spike 2	80	262	2.7%	4.2%
Spike 3	80	417	3.7%	4.3%
Spike 4	80	588	2.5%	4.0%
Spike 5	80	830	4.2%	4.8%

Limit of Quantitation (LoQ) and Limit of Detection (LoD)

The lower limits of quantitation and detection were established using CLSI guideline EP17-A2.[15]

LoQ

The LoQ was determined with an accuracy goal at the LoQ of ≤ 35% total error (Westgard model). The LoQ of the MyCare Insite Total Aripiprazole Test is 51 ng/mL.

LoD

The LoD is the lowest amount of analyte that can be reliably detected (≥ 95% of results greater than the limit of blank). The LoD of the MyCare Insite Total Aripiprazole Test is 24 ng/mL.

Measurement Range

The measurement range of the total aripiprazole test is 51 – 1,200 ng/mL.

Specificity

Metabolism

Aripiprazole is metabolized in the liver by CYP3A4 and CYP2D6. The major metabolite dehydroaripiprazole also has pharmacological activity.[1,3] At steady-state, its concentration is ~40% of the parent drug.[1] The other major metabolite, the acid product of N-dealkylation (OPC-3373), is also present in serum. Another minor metabolite (DCPP) is found at < 20% of the parent drug.

The antibody formulation in the Reagent Cap was tested for selectivity to metabolites. Specificity for the following metabolites was tested in the absence and presence of aripiprazole at 150, 500, and 1,000 ng/mL.[16]

Compound	Tested at (ng/mL)	Bias
3,4-dihydro-7-(3'carboxy)propoxy-2(1H) quinolinone (OPC-3373)	475	3%
1-(2,3-dichlorophenyl)piperazine (DCPP)	50	6%

Interfering Substances

Testing of interferences was conducted according to CLSI guidelines for interference.[17,18] No significant test bias was observed from samples with the following endogenous interferents at the given levels:

Interferent	Level	
Rheumatoid Factor	510 IU/mL	
Human Serum Albumin	6.1g/dL	61 g/L
Human Immunoglobulin G	6.1 g/dL	61 g/L
Bilirubin	44 mg/dL	753 µmol/L
Lipids	1,600 mg/dL	18.08 mmol/L
Hemolysate	1,050 mg/dL	
Red blood cells	11.5 – 18.5 g/dL	35% – 55%

Cross-reactivity and Interference

The antibody formulation in the Reagent Cap was tested for selectivity. Cross-reactivity for the following compounds was tested in the absence of aripiprazole and interference was tested in the presence of aripiprazole at 150, 500, and 1,000 ng/mL. The following compounds did not interfere with the MyCare Psychiatry Total Aripiprazole Assay Kit..[16]

In addition, ethanol was tested at 10 mg/mL in the presence (150 and 500 ng/mL) and absence of total aripiprazole. Test bias introduced by 10 mg/mL of ethanol in whole blood was < 10%.

Compound	Tested at (ng/mL)	Compound	Tested at (ng/mL)
Acetaminophen	200,000	Acetazolamide	60,000
Acetylsalicylic acid	500,000	Albuterol	1,000
Alendronate sodium	1,000	Alpha - tocopherol	130,000
Alprazolam	2,000	Amantadine Hydrochloride	10,000
Amikacin sulfate	144,000	Amiloride HCl dihydrate	500
Amisulpride	1,200	Amitriptyline	1,000
Amlodipine besylate	100	S (+)-amphetamine	1,000
Amoxapine	2,900	Amoxicillin	80,000
L-ascorbic acid	60,000	Asenapine	500
Atomoxetine	7,900	Atorvastatin calcium	800
Baclofen	3,000	Benztropine	600
Betamethasone	400	Biotin	3,600
Biperiden	300	Blonanserin	100
Brexpiprazole	1,000	Bromperidol	100
Budesonide	50	Bupropion	3,000
Buspirone	200	Caffeine	108,000
Calcium carbonate	315,000	Cannabidiol	100
Cannabinol	100	Carbamazepine	45,000
L-Carnosine	100,000	Cefalexin	200,000
Celecoxib	8,800	Cetirizine dihydrochloride	4,400
8-chloro-theophylline	3,000	Chlorpromazine HCl	3,300
Cimetidine	30,000	Ciprofloxacin	12,000
Citalopram HBr	5,500	Clindamycin	51,000
Clonazepam	300	Clotiapine	500
Clotrimazole	50	Clozapine	1,800
Codeine	2,000	Cortisol	300
(-)-cotinine	2,000	Cyclosporin A	9,000
Desloratadine	600	Desvenlafaxine	800
Dextromethorphan	1,000	Diazepam	30,000
Dextromethorphan	1,000	Diazepam	30,000
Diphenhydramine HCl	6,000	Divalproex Sodium	400,000
Docosahexaenoic acid ethyl ester	150,000	Donepezil	50,000
Doxycycline HCl	35,000	Droperidol	200
D-Serine	100,000	Duloxetine	200
Erythromycin	138,000	Escitalopram	200
Estradiol	10	Eszopiclone	200
Famotidine	2,500	Fenofibrate	50,000

Compound	Tested at (ng/mL)	Compound	Tested at (ng/mL)
Fentanyl	600	Fluoxetine HCl	4,000
Fluticasone propionate	50	Fluvoxamine	2,000
Folic acid	15	Furosemide	60,000
Galantamine	200	Gentamicin sulfate	30,000
Glyburide	2,000	Haloperidol	1,000
Heparin sodium salt	50 U/mL	Hydrochloro-thiazide	6,000
Hyoscine (Scopolamine HBr)	100	Hyperforin (St. John's Wort)	200
Hypericin (St. John's Wort)	100	Ibuprofen	500,000
Iloperidone	100	Imipramine	700
Indinavir sulfate	400	Lactulose	10,000
Lamivudine	10,500	Lamotrigine	15,000
Lansoprazole	9,400	Levonorgestrel	100
Lisinopril dihydrate	350	Lithium carbonate	250,000
Lorazepam	1,000	Lovastatin	500
Loxapine	300	Lurasidone	400
Meclizine dihydrochloride	500	Metformin	40,000
Methotrimeprazine	600	Methylphenidate HCl	350
Metoclopramide HCl	500	Metoprolol tartrate	5,000
Metronidazole	123,000	Midazolam	3,800
Milnacipran	10,000	Mirtazapine	900
Mometasone furoate	50	Morphine	7,800
Naltrexone	200	Naproxen sodium	500,000
Nateglinide	30,000	Nefazodone HCl	6,000
Nicotine	1,000	Nicotinic acid	27,900
Nordiazepam	5,000	Nortriptyline	1,200
Olanzapine	300	Omeprazole	8,400
Oxazepam	5,000	Oxcarbazepine	105,000
Oxycodone	500	Paliperidone	60
Pantothenic acid	1,800	Paroxetine	1,200
Penicillin V	42,000	Perazine	1,400
Perlapine	150	Perphenazine	100
Phenobarbital	690,000	Phentermine	500
Phenytoin	60,000	Pimozide	100
Pipamperone dihydrochloride	1,200	Potassium EDTA	1000
Pravastatin sodium	300	Prednisolone	3,000
Pregabalin	22,500	Procyclidine	1,900
Promethazine	1,200	R,R (-)-pseudoephedrine	10,000

Compound	Tested at (ng/mL)	Compound	Tested at (ng/mL)
S,S (+)-pseudoephedrine	10,000	Pyridoxine HCl	100
Quetiapine	2,800	Quinidine	15,000
Raloxifene	50	Ranitidine	10,500
Retinol	4,000	Riboflavin	200
Rifampicin	65,000	Risperidone	200
Rosuvastatin calcium	200	Salicylic acid	500,000
Sarcosine	1,500	Sertindole	300
Sertraline hydrochloride	1,000	Simvastatin	1,700
Sodium benzoate	400,000	Sodium fluoride	900
Spironolactone	600	Sulfamethoxazole	400,000
Sulpiride	50,000	Temazepam	5,000

Compound	Tested at (ng/mL)	Compound	Tested at (ng/mL)
Terbinafine	9,000	Theophylline	60,000
Thiamine HCl	500	Topiramate	75,000
Trazodone HCl	14,000	Triamcinolone acetonide	300
Triamterene	9,000	Triazolam	40
Valproic acid	500,000	Vancomycin HCl	120,000
Varenicline	50	Venlafaxine HCl	700
Vitamin B12	50	Vitamin D2	200
Vitamin K1	50	Warfarin	75,000
Ziprasidone	600	Zolpidem hemitartrate	5,000
Zonisamide	120,000	Zopiclone	200
Zuclopenthixol	300		

Recovery

The recovery of total aripiprazole was assessed in the two controls, and in the four total aripiprazole spiked whole blood samples that were measured for the EP05-A3 precision performance study. The percent recovery was determined by dividing the mean measured concentration of each sample by the expected concentration of total aripiprazole. The percent recovery ranged from 85 to 115%.

Linearity

The linearity of the aripiprazole test was verified according to CLSI guideline EP06-Ed2.[19] Fourteen linearity samples covering the measuring range were prepared in human whole blood spiked with total aripiprazole. Linear regression gave a slope of 1.007 (CI 95%: 0.956 to 1.023) and an intercept of -4 (CI 95%: -12 to 24) with an R = 0.9980. Deviation from linearity (n = 7) was ≤ 13%. The test was linear across the measuring range from 51 to 1,200 ng/mL**.**

Method Comparison

Results of the aripiprazole test were compared to a validated LC-MS/MS according to CLSI guideline EP09c.[20] Deming regression analysis was performed with 92 patient samples.

Deming Regression Statistics MyCare Insite Total Aripiprazole Test vs. LC-MS/MS	
Slope	0.92
Intercept	2
Correlation Coefficient (R)	0.9560
N	92
Concentration Range (LC-MS/MS)	17 – 909 ng/mL

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SYMBOLS USED

IVD	*in vitro* Diagnostic Device	LOT	Batch Code
	Consult Instructions for Use		Manufacturer
	Contains sufficient for <n> tests		Use By Date
	Temperature Limitation		Caution
REF	Catalog Number	EC REP	Authorized Representative in the European Community
	Do not re-use		Near Patient Testing
CE	CE mark	SDS	Safety Data Sheet

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